IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF WEST VIRGINIA

DEY, L.P., and DEY, INC.,

Plaintiffs,

v. // CIVIL ACTION NO. 1:09CV87
(Judge Keeley)

TEVA PARENTERAL MEDICINES, INC.,
TEVA PHARMACEUTICALS USA, INC., and
TEVA PHARMACEUTICAL INDUSTRIES, LTD.,

Defendants.

MEMORANDUM OPINION AND ORDER CONSTRUING PATENT CLAIMS

This patent infringement case involves four United States Patents issued to the plaintiffs, Dey L.P. and Dey, Inc. ("Dey"), including 6,667,344 ("the '344 patent"), 6,814,953 ("the '953 patent"), 7,348,362 ("the '362 patent"), and 7,462,645 ("the '645 patent") (collectively, the "patents-in-suit"). The '344 and '953 patents, entitled "Bronchodilating Compositions and Methods," derive from provisional U.S. patent application 60/284,606, and share essentially identical specifications. The '362 and '645 patents, entitled "Bronchodilating Beta-Agonist Compositions and Methods," derive from provisional U.S. patent application 60/486,386. They too share essentially identical specifications that closely resemble those of the '344 and '953 patents.

The patents-in-suit cover aqueous compositions of formoterol, which allow the compositions to remain suitable for direct administration during long-term storage. They also cover methods

for using these compositions to treat broncho-constrictive disorders. Dey uses the formulations and methods described in these patents in a commercial product known as Perforomist®.

I. BACKGROUND

In a letter dated May 12, 2009, the defendants, Teva Parenteral Medicines, Inc., Teva Pharmaceuticals USA, Inc., and Teva Pharmaceutical Industries, LTD. (collectively, "Teva"), notified Dey that they had filed an Abbreviated New Drug Application ("ANDA") seeking United States Food and Drug Administration ("FDA") approval to market a generic formoterol fumarate inhalation solution 0.02 mg/2mL ("generic formoterol fumarate product"). Teva also filed a certification with the FDA alleging certain claims of the four patents-in-suit are invalid, unenforceable and not infringed by Teva's manufacture or sale of its generic formoterol fumarate product. Dey in response filed this patent infringement action against Teva pursuant the Hatch-Waxman Act (the "Hatch-Waxman Act"). See 21 U.S.C. §§ 355, 360cc; 35 U.S.C. §§ 156, 271.

Dey contends that the product described in Teva's ANDA infringes claims in the four patents-in-suit, specifically claims 1-14, 16-22, 27-31, 33-39, 48, 61-62, 65, and 69-74 of the '344 patent, claims 1-13, 15-21, 26-30, 32-38, 58-63, 74-86, 90-94, 99-

103, 105-111, and 131-136 of the '953 patent, claims 1-15 of the '362 patent, and claims 1-3, and 5-9 of the '645 patent (collectively, the "asserted claims").

The parties have identified four terms and phrases from the asserted claims in need of construction for which they have proposed competing claim constructions. They also have submitted six agreed claim constructions. Following a claims construction hearing on March 3, 2011, and after considering the parties' briefs and arguments, the Court adopts the following constructions.

II. LEGAL STANDARDS

The construction of patent claims presents a matter of law governed by federal statutes and the decisions of the Supreme Court of the United States and the United States Court of Appeals for the Federal Circuit. See Markman v. Westview Instruments, Inc., 52 F.3d 967, 979 (Fed. Cir. 1995). When interpreting the meaning of a claim, a court may consider the claims, the specifications, and the prosecution histories as intrinsic evidence. Id. (quoting Unique Concepts, Inc. v. Brown, 939 F.2d 1558, 1561 (Fed. Cir. 1991)). According to a fundamental principle of claim construction, the invention itself, and the scope of a patentee's right of exclusion, will be defined by the patent's claims. See Phillips v. AWH Corporation, 415 F.3d 1303, 1312 (Fed. Cir. 2005)

(en banc) (quoting Innova/Pure Water, Inc. v. Safari Water Filtration Sys., Inc., 381 F.3d 1111, 1115 (Fed. Cir. 2004)); see also Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1582 (Fed. Cir. 1996) ("[W]e look to the words of the claims themselves . . . to define the scope of the patented invention."). The description of an invention in the claims, therefore, limits the scope of the invention. Id.

Claim terms should be construed according to their "ordinary and customary" meaning, which is "the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention." Id. at 1313. Claim construction therefore requires a court to determine how a person of ordinary skill in the art would have understood the disputed term or phrase in question. "Importantly, the person of ordinary skill in the art is deemed to read the claim term not only in the context of the particular claim in which the disputed term appears, but in the context of the entire patent, including the specification." Id.

When construing patent claims then, a court must consider the context of the entire patent, including both asserted and unasserted claims. Id. at 1314. Because a patent will ordinarily use patent terms consistently, "the usage of a term in one claim can often illuminate the meaning of the same term in other claims."

Id. at 1314. Accordingly, "[d]ifferences among claims" can provide insight into "understanding the meaning of particular claim terms," and "the presence of a dependent claim that adds a particular limitation gives rise to a presumption that the limitation in question is not present in the independent claim." Id. at 1314-15 (citing Liebel-Flarsheim Co. v. Medrad, Inc., 358 F.3d 898, 910 (Fed. Cir. 2004)).

Aside from the claims themselves, the specification in the patent often provides the "'best source for understanding a technical term.'" Id. at 1315 (quoting Multiform Desiccants,Inc. v. Medzam, Ltd., 133 F.3d 1473, 1478 (Fed. Cir. 1998)). Pursuant to 35 U.S.C. § 112, ¶ 1, an inventor must use the specification to describe his claimed invention in "full, clear, concise, and exact terms." Accordingly, "[t]he claims of a patent are always to be read or interpreted in the light of its specifications." Schriber-Schroth Co. v. Cleveland Trust Co., 311 U.S. 211, 217 (1940).

An inventor may alter the "ordinary and customary" meaning of a term, however, by acting as his own lexicographer. This occurs, for example, when the patent specification defines a term in a manner different from its ordinary and customary meaning. Phillips, 415 F.3d at 1316. Thus, it is "entirely appropriate for a court, when conducting claim construction, to rely heavily on the

written description for guidance as to the meaning of the claims." Id. at 1317.

Nevertheless, a court may not import a limitation into the claims from the specification. Id. at 1323. Moreover, the Federal Circuit has "repeatedly warned" against limiting the claims to the embodiments specifically described in the specification. Id. In other words, a court should not construe the patent claims as being limited to a single embodiment simply because the patent describes only one embodiment. Id. (citing Gemstar-TV Guide Int'l Inc. v. Int'l Trade Comm'n, 383 F.3d 1352, 1366 (Fed. Cir. 2004)).

The prosecution history of a patent may also provide insight into the meaning of a term or phrase. "Like the specification, the prosecution history provides evidence of how the PTO and the inventor understood the patent." Id. at 1317. The inventor's limitation of the invention during the patent's prosecution may suggest that a claim has a narrower scope than it otherwise might have. Id.

Finally, when determining the ordinary and customary meaning of a term, a court must be cautious when considering extrinsic evidence, such as expert testimony, dictionaries, and learned treatises. Id. Nevertheless, such sources may be reliable if they were publicly available and show "'what a person of skill in

the art would have understood disputed claim language to mean.'" Id. at 1314 (quoting Innova, 381 F.3d at 1116).

It is with these legal principles in mind that the Court turns to the construction of the four disputed terms or phrases among the asserted claims of the patents-in-suit.

III. ANALYSIS

A. "Formulated at a concentration suitable for direct administration"

Dey proposes that the phrase "formulated at a concentration suitable for direct administration," as used in claim 1 of the '344 patent and claim 74 of the '953 patent means "ready to administer directly to a subject in need thereof, without mixing or diluting."[1] Teva construes the phrase to mean "the composition is formulated at a concentration that is capable of being administered directly to a subject in need thereof."

According to Dey, its proposed construction is supported by the claims, the specifications, the prosecution histories of the patents-in-suit, and the inventors' sworn deposition testimony. It argues that Teva's proposed construction improperly treats "capable

[1] Initially, Dey proposed the following construction: "ready to administer directly to a subject in need thereof, without mixing or diluting, at a free-base concentration of about 5 µg/mL to about 2mg/mL." It has since, however, withdrawn the last phrase. See Transcript of Record at 10-11, Dey, et al. v. Teva, et al., No. 1:09CV87 (N.D.W. Va. Mar. 3, 2011) (dkt. no. 95).

of" as a synonym for "suitable for." Teva claims that the intrinsic evidence supports its proposed construction, and that Dey has impermissibly added limitations that have no intrinsic basis.

1. The Claims

According to Dey, the claims themselves support its proposed construction because the ordinary meaning of the term "formulated" is "made, manufactured, devised, composed, produced, or fabricated." Pl.'s Opening Claim Construction Report at 5 (citing Cambridge Dictionary of American English 339 (Cambridge University Press 2000) (dkt. no. 69-5) (dkt. no. 69). Teva, however, argues that the phrase "without mixing or diluting" in Dey's proposed construction improperly shifts the claim's focus from the time of the composition's manufacture to the time after formulation, which Teva contends is irrelevant to "whether the composition was 'formulated at a concentration suitable for direct administration.'" Def.'s Rebuttal Report at 10 (dkt. no. 76). Teva also argues that Dey's construction renders the claims indefinite because a person of ordinary skill in the art could only know if another composition infringed Dey's composition by discovering how the composition is used. See IPXL Holdings, L.L.C. v. Amazon.com, Inc., 430 F.3d 1377, 1384 (Fed. Cir. 2005) (holding that a claim is invalid when it is indefinite and fails to "apprise

a person of ordinary skill in the art of its scope").

Dey denies that its proposed construction focuses on what happens to a composition after its formulation, claiming it clarifies how a composition must be created or made in order to be "suitable for direct administration." It contends that a composition is created or made to be "suitable for direct administration" when it is "ready to administer" without the need for "mixing or diluting."

The claims themselves, unfortunately, fail to shed sufficient light on the meaning of this requirement. The Court therefore must look beyond the claims to the specifications and prosecution histories of the patents-in-suit to construe this phrase.

2. The Specifications

According to Dey, the specifications provide intrinsic support for its proposed construction. A specification may define a claim term explicitly or by implication. Astrazeneca AB, Aktiebolaget Hassle, KBI-E, Inc. v. Mutual Pharm. Co., Inc., 384 F.3d 1333, 1339-40 (Fed. Cir. 2004). Moreover, "[w]here the general summary or description of the invention describes a feature of the invention . . . and criticizes other products . . . that lack that same feature, this operates as a clear disavowal of these other products[.]" Id. In any event, "the claims cannot be of broader

scope than the invention that is set forth in the specification." On Demand Machine Corp. v. Ingram Industries, Inc., 442 F.3d 1331, 1340 (Fed. Cir. 2006).

Here, the specifications describe the prior art of Hochrainer in U.S. Patent No. 6,150,418 ("Hochrainer") as:

> a "liquid active substance concentrate" containing formoterol in the form of its free base, or in the form of one of the pharmacologically acceptable salts or addition products (adducts) thereof as active substance.

'344, col. 7, ll. 65-67, col. 8., ll. 1-2. They also describe Hochrainer's formoterol concentrate as unsuitable for direct administration:

> The specification [of Hochrainer] provides . . . that it is the high concentration that allows for the stability of the concentrate. **The "liquid active substance concentrate" is not suitable for direct administration to a patient**.

Id. at col. 8, ll. 7-10 (emphasis added).

In contrast, the specifications in the '344 and '953 patents expressly provide that Dey's compositions are "suitable for direct administration to a subject in need thereof." Id. at col. 2, ll. 24-29; '953, col 2, ll. 35-37. Dey argues that this distinction provides helpful insight for determining what a person of ordinary skill in the art would understand the phrase "suitable for direct

administration" to mean. See Arthur A. Collins, Inc. v. Northern Telecom Limited, 216 F.3d 1042, 1045 (Fed. Cir. 2000) (recognizing that a patentee's citation to the prior art can provide helpful guidance for determining a claim term's meaning to a person of ordinary skill in the art).

The specification in Hochrainer provides that "[t]he active substance concentrate according to the invention may be converted, by **diluting** with a pharmacologically acceptable liquid." Hochrainer, col. 1, ll. 47-49 (emphasis added). It clarifies that "'highly concentrated'" means "a concentration of the active substance which is usually too high to enable the corresponding solution or suspension to be used therapeutically for inhalation **without being diluted**." Id. at col. 2, ll. 1-4 (emphasis added).

Hochrainer also provides that "[t]he active substance concentrate according to the invention is **not** usually **suitable** as such for **direct** medicinal use," and that "[a] preferred method of converting the active substance concentrate into a **pharmaceutical preparation suitable for administration** is by **diluting** the active substance concentrate according to the invention with a pharmacologically suitable solvent or suspension agent." Id. at col. 4, ll. 9-11, 21-25. It also repeatedly provides that the active substance concentrate may be diluted by mixing it with a

"diluent." See id. at col. 5, ll. 1-5, 20-27, 42-45, 57-67, col. 6, ll. 16-21.

These properties establish that the inventors of Dey's compositions viewed Hochrainer's formoterol concentrate as unsuitable for direct administration because it usually needed to be mixed with a diluent prior to administration to a patient. Dey argues to persuasive effect that, because the '344 and '953 patents distinguish themselves from Hochrainer based on their suitability for direct administration, a person of ordinary skill in the art would understand that a composition is "formulated at a concentration suitable for direct administration" when it is "ready to administer directly to a subject in need thereof, without mixing or diluting."

3. The Prosecution Histories

Beyond the specifications and prior art, further support for Dey's proposed construction can be found in the prosecution histories of the patents-in-suit. See Ormco Corporation v. Align Technology, Inc., 498 F.3d 1307, 1314 (Fed. Cir. 2007). "Like the specification, the prosecution history provides evidence of how the PTO and the inventor understood the patent." Phillips, 415 F.3d at 1317; see also Sentry Prods., Inc. v. Eagle Mfg. Co., 400 F.3d 910, 915 (Fed. Cir. 2005) (holding that the prosecution history may

modify a claim term's scope if the patentee "expressly disclaimed" the prior art's subject matter).

In its application for the '344 patent, Dey initially submitted the following as claim 1:

> 1. A pharmaceutical composition, comprising formoterol, or a derivative thereof, in a pharmacologically suitable fluid, wherein the composition is stable during long term storage and the fluid comprises water.

Dey, '344 Application (dkt. no. 69-6). Similarly, in its application for the '953 patent, it initially submitted the following as claim 1:

> 1. A kit, comprising:
> (a) an aqueous composition comprising formoterol or a derivative thereof formulated for single dosage administration; and
> (b) a nebulizer.

Dey, '953 Application (dkt. no. 69-10). The U.S. Patent and Trademark Office rejected these claims as anticipated by Hochrainer.

In its response to this rejection, Dey added the phrase "formulated at a concentration suitable for direct administration to a subject in need thereof" to claim 1 in each patent:

> 1. (Amended) A pharmaceutical composition, comprising formoterol, or a derivative thereof, in a pharmacologically suitable fluid, wherein the composition is stable during long term storage, the fluid

> comprises water, and the composition is **formulated at a concentration suitable for direct administration to a subject in need thereof**.

Dey, Amendment at 2 (June 22, 2001) (dkt. no. 69-8) (emphasis added).

> 1. (Amended) A kit, comprising:
> (a) an aqueous composition comprising formoterol or a derivative thereof **formulated at a concentration suitable for direct administration to a subject in need thereof**, wherein the composition is stable during long term storage; and
> (b) a nebulizer.

Dey, Amendment at 1 (May 3, 2002) (dkt. no. 69-12) (emphasis added).

At the time it submitted its amended version of claim 1 for the '344 patent, Dey also stated:

> Hochrainer et al. discloses that it is the high concentration that allows for the stability of the concentrate. The **cited reference does not disclose stable, aqueous compositions** containing formoterol **formulated at a concentration for direct administration to a subject in need thereof**, **as required by the instantly-claimed compositions**.
>
> The "highly concentrated" "**active substance concentrate**" of the reference is **not suitable for direct administration** to a subject in need thereof.
>
> . . .

> Thus, the **"active substance concentrate" of Hochrainer et al. is merely a means for the storage of highly concentrated solutions of formoterol**, and is **not formulated at a concentration for direct administration to a subject in need thereof**.

Dey, Amendment at 14-15 (June 22, 2001) (dkt. no. 69-8) (emphasis added) (prosecution history for the '344 patent) (dkt. no. 69-8). Dey provided a similar response to the U.S. Patent and Trademark Office following rejection of the '953 patent application. Dey, Amendment at 8-10 (May 3, 2002) (dkt. no. 69-12) (prosecution history of the '953 patent). After receiving these responses, the examiners at the U.S. Patent and Trademark Office approved Dey's amended claims.

Dey supported its construction during the claims construction hearing by analogizing Hochrainer's formoterol concentrate to frozen orange juice concentrate that must be mixed or diluted with water prior to being suitable for drinking. Dey then compared its own compositions to orange juice that may be consumed directly from a bottle, without the need for mixing or diluting. See Transcript of Record at 18, Dey, et al. v. Teva, et al., No. 1:09CV87 (N.D.W. Va. Mar. 3, 2011) (dkt. no. 95). Dey contended that it is this vital difference that renders its compositions of formoterol "suitable for direct administration" and therefore "ready to use."

In response to this analogy, Teva pointed out that people commonly mix orange juice with vodka prior to consuming it. Id. at 73. According to Teva, vodka is suitable for direct consumption regardless of whether a person later mixes or dilutes it with orange juice, and because of this the phrase "suitable for direct administration" would not preclude an end user from further diluting or mixing Dey's compositions. According to Teva, Dey's focus on how the compositions must be used prior to administration renders the patents indefinite. See IPXL Holdings, 430 F.3d at 1384.

While Teva is correct that the construction of the phrase "formulated at a concentration suitable for direct administration" does not hinge on what happens to the compositions after formulation, its argument is ultimately unpersuasive. The disputed phrase begins with the term "formulated," and there is no indication in the intrinsic evidence that Dey modified the ordinary meaning of this term, which commonly means "created."[2] See Phillips, 415 F.3d at 1314 (citing Brown v. 3M, 265 F.3d 1349, 1352 (Fed. Cir. 2001) (recognizing that claim meaning will sometimes be "readily apparent even to lay judges," and that "claim construction

[2] See also Cambridge Dictionary of American English 339 (Cambridge University Press 2000) (defining "formulated") (dkt. no. 69-5).

in such cases involves little more than the application of the widely accepted meaning of commonly understood words."). In point of fact, the term "formulated" in the disputed phrase clarifies that suitability for "direct administration" turns on how the compositions must be created. Once the compositions are formulated in a way that renders them "suitable for direct administration," it is irrelevant to the analysis what may happen to them afterward. Stated another way, the phrase "formulated at a concentration suitable for direct administration" does not restrict usage of the compositions after formulation but rather provides a guidepost for how the compositions must be "formulated."

Given that, the question becomes what properties and characteristics must the compositions possess in order to be "formulated at a concentration suitable for direct administration?" The repeated disavowal in the intrinsic evidence of the "active substance concentrate" of Hochrainer persuades the Court that Dey's compositions are "suitable for direct administration" because, unlike the prior art of Hochrainer's concentrate, they are "formulated" at a concentration that renders it unnecessary to mix or dilute them prior to administration. Thus, they are "ready to use" in the same way that liquid orange juice is "ready to use," without diluting or mixing prior to consumption. Once formulated,

it is irrelevant to Dey's compositions whether an end user mixes or dilutes them further because it is at the time of manufacture that they must be "ready to administer, without mixing or diluting."

Teva's proposed construction not only lacks evidentiary support, it also is not consistent with the intrinsic evidence. At bottom, it substitutes "capable of" for "suitable for." Under that construction, the concentrate in Hochrainer also would be "capable of" direct administration because it could be so administered after mixing or dilution. Teva's construction, thus, fails to reconcile Dey's important disavowal of Hochrainer's formoterol concentrate in the intrinsic evidence, and conflicts with what a person of ordinary skill in the art would understand the disputed phrase to mean.

In conclusion, although "ready to administer directly" and "without mixing or diluting" do not appear in either the '344 or '953 patents, the specifications and prosecution histories of these patents establish that a person of ordinary skill in the art would understand the phrase "formulated at a concentration suitable for direct administration" to mean that the compositions must be "ready to use," and that the compositions are "ready to use" when they can be administered without diluting or mixing. See Ormco, 498 F.3d at 1314. The Court therefore adopts Dey's proposed construction

that a composition is "formulated at a concentration suitable for direct administration" when it is "ready to administer directly to a subject in need thereof, without mixing or diluting."[3]

B. "Pharmaceutical composition"

Dey construes the term "pharmaceutical composition," as used in claim 1 of the '344 patent, claim 74 of the '953 patent, claim 1 of the '362 patent, and claim 1 of the '645 patent, to mean "a medicinal formulation containing an active drug and inert excipients." Teva construes it to mean "a stable composition."

Dey argues that the intrinsic evidence does not change or modify the plain and ordinary meaning of "pharmaceutical composition," and that Teva's proposed construction inappropriately seeks to construe a preamble phrase. While Teva does not dispute that Dey's construction is the plain and ordinary meaning of the term, it claims the intrinsic evidence of the patents-in-suit establish that the inventors modified that meaning to include only compositions that are themselves intrinsically stable. Further, it argues the term constitutes a necessary antecedent that provides

[3] Because the Court adopts Dey's proposed construction, it need not consider the testimony of the inventors. See Howmedica Osteonics Corp. v. Wright Med. Tech., Inc., 540 F.3d 1337, 1346-47 (Fed. Cir. 2008) (recognizing that consideration of inventor testimony is often inappropriate and unnecessary during claim construction).

structure for subsequent claim terms.

There is a "'heavy presumption' that a claim term carries its ordinary and customary meaning." CCS Fitness, Inc. v. Brunswick Corp., 288 F.3d 1359, 1366 (Fed. Cir. 2002). This presumption does not apply, however, where "the patentee acted as his own lexicographer and clearly set forth a definition of the disputed claim term in either the specification or prosecution history." Id. (citing Johnson Worldwide Associates, Inc. v. Zebco Corp., 175 F.3d at 990 (Fed. Cir. 1999)). To determine whether a disputed term has a definition different from its ordinary and customary meaning, courts may consider the claims, the specification, and the prosecution history. See Bell Atlantic Network Services, Inc. v. Covad Communications Group, Inc., 262 F.3d 1258, 1268-69 (Fed. Cir. 2001).

1. The Claims

According to Teva, the term "pharmaceutical composition" provides a claim limitation of overarching stability that is distinct from the mere requirements of stability "during long term storage" and "shelf life." Dey argues that this construction imports an unwarranted "stability" limitation where the term "stable" appears in the claims only in conjunction with the phrase "stable during long term storage." Further, because

"pharmaceutical composition" appears in preamble phrases, Dey contends it is a general term that does not limit the scope of the claims. Finally, Dey asserts the claims themselves support its construction of a "pharmaceutical composition" comprising an active drug, formoterol, and inert excipients, including a polar solvent, a tonicity adjusting agent, and a buffer. See, e.g., '344, cls. 1, 5, 7, 10.

Generally, "'the preamble does not limit the claims.'" See Am. Med. Sys., Inc. v. Biolitec, Inc., 618 F.3d 1354 (Fed. Cir. Sept. 13, 2010) (quoting Allen Eng'g Corp. v. Bartell Indus., Inc., 299 F.3d 1336, 1346 (Fed. Cir. 2002)). Therefore, to determine whether a preamble constitutes a substantive limitation, a court must evaluate the entire patent in order to understand the scope of the invention and the inventors' intent as to the meaning and scope of the claims. See Catalina Mktg. Int'l, Inc. v. Coolsavings.com, Inc., 289 F.3d 801, 808 (Fed. Cir. 2002) (quoting Corning Glass Works v. Sumitomo Electric U.S.A., Inc., 868 F.2d 1251, 1257 (Fed. Cir. 1989)).

A preamble phrase does not constitute a substantive limitation when it states the invention's "purpose or intended use," and the body of the claim completely defines the claimed invention. Id.; see also Biolitec, 299 F.3d at 1346 (quoting

Catalina, 289 F.3d at 809) (holding that "[a] preamble is not regarded as limiting . . . '[w]hen the claim body describes a structurally complete invention such that deletion of the preamble phrase does not affect the structure or steps of the claimed invention.'"). Nor does it constitute a substantive limitation when by using a "descriptive name" it identifies a complete invention set forth in the body of the claims. Id. (quoting IMS Tech., Inc. v. Haas Automation, Inc., 206 F.3d 1422, 1434-35 (Fed. Cir. 2000)). However, a phrase does constitute a substantive limitation if it includes "essential structure or steps, or if it is 'necessary to give life, meaning, and vitality' to the claim.'" Catalina, 289 F.3d at 808 (quoting Pitney Bowes, Inc. v. Hewlett-Packard Co., 182 F.3d 1298, 1309 (Fed. Cir. 1999)).

In the patents-in-suit, the term "pharmaceutical composition" appears both as preamble phrases and also in the body of the claims. For example, the '344 patent describes a "pharmaceutical composition" as being comprised of:

> 1. . . . formoterol, or a derivative thereof, in a pharmacologically suitable fluid, wherein the composition is stable during long term storage, the fluid comprises water, and the composition is formulated at a concentration suitable for direct administration to a subject in need thereof.

'344, cl. 1 (emphasis added) (preamble). Similarly, the '953

patent describes

> [a] method for the treatment, prevention, or amelioration of one or more symptoms of bronchoconstrictive disorders, comprising administering an effective amount of a pharmaceutical composition to a subject in need of such treatment, wherein the **pharmaceutical composition** comprises formoterol or a derivative thereof formulated at a concentration suitable for direct administration to a subject in need thereof, in a pharmacologically suitable fluid, wherein the composition is stable during long term storage and the fluid comprises water.

'953, cl. 74 (emphasis added) (body). Thus, to resolve whether the term "pharmaceutical composition" constitutes a "life-giving" limitation or a non-limiting and general description, the Court must review the patent as a whole. See Catalina, 289 F.3d at 808.

2. The Specifications

Teva contends the specifications only describe pharmaceutical compositions that are themselves intrinsically stable. Further, it contends that the specifications contrast the prior art of Hochrainer to Dey's compositions based on stability, and also describe the other formulation excipients based on their stability as well.

In pertinent part, the specifications state that

> [t]he compositions provided herein are **stable** solutions of a bronchodilating agent, or a derivative thereof, in a pharmacologically

> suitable fluid that contains water, that are **stable during long term storage**.

'344, col. 2, ll. 23-28 (emphasis added); '953, col. 2, ll. 32-35 (emphasis added). It is precisely because the specifications provide that the compositions are "stable" and "stable during long term storage" that Teva argues the term "pharmaceutical composition," as used in the patents-in-suit, includes an overarching requirement of stability distinct from the requirement of merely being "stable during long term storage." It also contends that the specifications themselves define this overarching requirement of stability:

> As used herein, the stability of a composition provided herein refers to the length of time at a given temperature that is greater than 80%, 85%, 90% or 95% of the initial amount of active ingredient, e.g., formoterol, is present in the composition. Thus, for example, a composition that is stable for 30 days at 25◦ C. would have greater than 80%, 85%, 90% or 95% of the initial amount of active ingredient present in the composition at 30 days following storage at 25◦ C.

'344, col. 5, ll. 30-38; '953, col. 5, ll. 40-48.

While Dey agrees that the compositions must be "stable," it argues that this characteristic derives from the requirement that the compositions be "suitable for direct administration." According to Dey, "stability" is not a characteristic that is inherent in the term "pharmaceutical composition." It contends the

term itself implies no limitation of stability, and only appears in the claims as a general term. Dey also contends that Teva's suggested requirement of overarching stability fails to illuminate the term's meaning because the patents-in-suit do not establish durations or temperature limits for measuring it. Absent such context, Teva's stability requirement is meaningless in Dey's view.

After careful consideration of the specifications, the Court concludes that the inventors did not define "pharmaceutical composition" to mean a "stable composition" with the reasonable clarity, deliberateness, and precision required when an inventor applies his own lexicography to a claim term. See In re Paulson, 30 F.3d 1475, 1480 (Fed. Cir. 1994). Whether it appears in the preamble of some claims, or in the body of others, the term provides only the general context of the inventions, not a substantive limitation. Compare '344, cl. 1 (preamble) with '953, cl. 74 (body).

3. The Prosecution Histories

The prosecution histories of the patents-in-suit further undermine Teva's proposed construction. Teva contends that during the prosecution of the patents Dey argued that the "stability" of its compositions distinguished them from the prior art because Hochrainer "does not disclose stable, aqueous compositions

containing formoterol[.]" Dey, Amendment at 14 (June 22, 2001) (dkt. no. 69-8) ('344 prosecution history).

Teva's emphasis on this excerpt from the prosecution history ignores the full context of Dey's argument, which includes the following:

> The **cited reference does not disclose stable, aqueous compositions** containing formoterol **formulated at a concentration for direct administration to a subject in need thereof, as required by the instantly-claimed compositions**.

Id. (emphasis added). Tellingly, as to the '344 patent, Dey never distinguished its compositions from the prior art based on stability alone, but relied on stability coupled with suitability for direct administration. Dey also made this same distinction during the prosecution of the '953 patent. See Dey, Amendment (May 3, 2002) (dkt. no. 69-12) ('953 prosecution history).

While prosecuting the '362 patent, Dey acknowledged that Hochrainer's concentrations were stable, but distinguished its own compositions based on characteristics of stability coupled with their suitability "for direct administration." Dey, Amendment (July 9, 2004) (dkt. no. 68-14) ('362 prosecution history); see also Dey, Amendment at 12 (Mar. 23, 2007) (dkt. no. 71) (stating that, unlike the prior art of Hochrainer, the compositions of the

'362 patent would be stable during long term storage and be "ready-to-use"). Dey never asserted that its pharmaceutical compositions had an inherent characteristic of "stability" distinct from being "stable during long term storage."

The prosecution histories, thus, fail to support Teva's argument. The term "pharmaceutical composition" is a general one, and, as discussed, none of the intrinsic evidence supports a construction otherwise. The Court therefore adopts Dey's proposed construction that the term "pharmaceutical composition" means "a medicinal formulation containing an active drug and inert excipients."

C. "Shelf life"

Dey construes the term "shelf life," as used in claim 2 of the '344 patent, claims 2 and 75 of the '953 patents, claims 1-3 and 9-10 of the '362 patents, and claims 2-3 of the '645 patent, to mean "the period of time during which a drug may be stored and remains suitable for use."[4] It points out that certain claims require the

[4] The '344 and '953 patents use the term "shelf-life," while the '362 and '645 patents use the term "shelf life." Compare '344 patent, cl. 2; '953 patent, cl. 2 with '362 patent, cl. 1; '645 patent, cl. 2. This opinion will use the preferred dictionary form of the term, "shelf life." See, e.g., Merriam-Webster's Third International Dictionary, Unabridged 2092 (Merriam-Webster, Inc., 3d ed. 2002); Merriam-Webster's Medical Desk Dictionary 740 (Merriam-Webster, Inc., 1996).

compositions to exhibit adequate "shelf life," see '344 patent, cl. 2; '953 patent, cl. 75, and refutes Teva's contention that, because the claims themselves state the shelf life durations of the compositions, those durations define the term. See '344, cl. 2 (stating that "the composition has an estimated shelf[]life of greater than 1 month usage time at 25° C and greater than or equal to 1 year storage time at 5° C."); '953, cls. 2, 75 (same); '362 Patent, cl. 1 (stating that the composition has "an estimated shelf life of greater than 90% after 3 months storage at 25° C and after 3 years storage at 5° C.").

Relying on Merriam-Webster's Medical Desk Dictionary, Dey asserts that the ordinary meaning of "shelf life" is "the period of time during which a material (as a food or drug) may be stored and remains suitable for use." Merriam-Webster's Medical Desk Dictionary 740 (Merriam-Webster, Inc., 1996). It further asserts that neither the claims, specifications, nor the prosecution histories of the patents-in-suit modify this common definition.

Notably, Teva does not propose a construction for the term "shelf life." Rather, pointing to the claims, it argues that reliance on a dictionary definition is improper because the claims themselves provide the definition. See TAP Pharm. Prods., Inc. v. Owl Pharm., L.L.C., 419 F.3d 1346, 1354 (Fed. Cir. 2005) (reasoning

that "a word describing patented technology takes its definition from the context in which it was used by the inventor."). Teva also asserts that Dey is seeking to have the Court rewrite, not merely interpret, the plain language of the claims. For example, as to claim 2 of the '344 patent, it contends that the shelf life durations of 1 month usage time at 25° C, and greater than or equal to 1 year storage time at 5° C, constitute distinct requirements, which Dey's proposed construction improperly conflates by "requiring that the composition be stored and remain suitable for use for more than 1 month usage time at 25° C and at least 1 year at 5° C[.]" Def.'s Rebuttal Brief at 20 (dkt. no. 76).

The interpretation of a claim's meaning begins with how a person of ordinary skill in the art would understand it. See Phillips, 415 F.3d at 1313 (citations omitted). While extrinsic sources, such as technical dictionaries, can provide a court with an educational resource for determining how a person of ordinary skill in the art would understand a claim term or phrase, such sources are inherently less reliable than the intrinsic evidence. Id. at 1319. Thus, a court may never use a dictionary definition to alter the meaning of a claim provided by an intrinsic source. Id.; see also C.R. Bard, 388 F.3d at 862. When construing a commonly used term, however, a court may sometimes construe it by

applying its "widely accepted meaning." Phillips, 415 F.3d at 1314 (citing Brown v. 3M, 265 F.3d 1349, 1352 (Fed. Cir. 2001)).

Teva's contentions, that, first, the Court need not construe the term because the claims and specifications already define it, and, second, the definition of "shelf life" has separate requirements for "usage time" and "storage time" which Dey merges into one, are unavailing. The argument that the "shelf life" durations for "storage time" and "usage time" constitute distinct requirements fails to explain why these terms are distinct or why these purported distinctions are significant. Moreover, while contending that the Court need not construe the term, Teva fails to explain how the "shelf life" durations on which it relies define it.

On this issue, the intrinsic evidence, unfortunately, is not helpful. Dey's construction, even though based on an extrinsic source, a medical dictionary, does provide a common definition establishing the significance of the "shelf life" durations cited by Teva, while neither modifying nor contradicting the intrinsic evidence. Its proposed construction also establishes that a composition stored at "5° C" for "1, 2 or 3 years," see '344 patent, col. 6, ll. 66-67, col. 7, ll. 1-4, would remain suitable for use, a fact that could not otherwise be determined if the Court

does not construe the term. Dey's construction of "shelf life," thus, is both consistent with the intrinsic evidence and also clarifies the significance of the "shelf life" durations. The Court therefore concludes that "shelf life" means "the period of time during which a drug may be stored and remains suitable for use."

D. "Formulated for single dosage administration"

Dey construes the phrase "formulated for single dosage administration," as used in claims 62, and 65 of the '344 patent, to mean "formulated in a quantity that is taken or administered at one time." Teva's construction is "the formoterol fumarate is formulated for single dosage administration via nebulization at a concentration of about 100 µg/mL." Neither party's arguments are grounded substantially in the intrinsic evidence; Teva relies exclusively on a single embodiment found in the specification, while Dey relies on extrinsic evidence to interpret the specification's examples and construe the disputed phrase.

1. The Claims

Dey points out that Teva's construction would render claim 66 of the '344 patent internally inconsistent, and therefore invalid, because it would require a composition "formulated for single dosage administration" to have a formoterol concentration of "about

100 µg/mL." Claim 66 of the '344 patent provides:

> 66. An article of manufacture, comprising packaging material, the composition of **claim 53 formulated for single dosage administration**, which is useful for treatment, prevention or amelioration of one or more symptoms of diseases or disorders associated with undesired and/or uncontrolled bronchoconstriction[.]

'344, cl. 66 (emphasis added). It depends from claim 53, which depends from claim 42. See Wahpeton Canvas Co., Inc. v. Frontier, Inc., 870 F.2d 1546, 1553 (Fed. Cir. 1989) ("a dependent claim includes all the limitations of the claim from which it depends."). Claim 42 provides:

> 42. The pharmaceutical composition of **claim 41**, wherein the **formoterol free base concentration** is **about 59 µg/mL**.

'344, cl. 42 (emphasis added). Because claim 66 depends from claims 53 and 42, the composition of claim 66, which is "formulated for single dosage administration," must have a "formoterol free base concentration" of "about 59 µg/mL." Teva concedes that its construction would render claim 66 internally inconsistent and invalid, but it argues that its construction is the only one "that is consistent with the claim's language and the written

description."[5] Rhine v. Casio, Inc., 183 F.3d 1342, 1345 (Fed. Cir. 1999).

The Federal Circuit instructs that "claims are generally construed so as to sustain their validity, if possible." Whittaker Corp. by Technibilt Div. v. UNR Industries, Inc., 911 F.2d 709, 711-12 (Fed. Cir. 1990) (citing ACS Hosp. Sys., Inc. v. Montefiore Hosp., 732 F.2d 1572, 1577 (Fed. Cir.1984)). This axiom only applies, however, when a claim's construction is consistent with the claim's language and the written description. Rhine, 183 F.3d at 1345. In other words, a court may not rewrite a claim to preserve its validity. Id. (citing Becton Dickinson & Co. v. C.R. Bard, Inc., 922 F.2d 792, 799 & n.6 (Fed. Cir. 1990)). Here, because the claims themselves provide little insight into the meaning of the disputed phrase, the Court must examine the specification to determine whether it explicitly defines "formulated for single dosage administration" as urged by Teva.

2. The Specification

Dey relies on extrinsic sources to argue that examples from the specification support its construction that "formulated for

[5] As discussed earlier, although Dey does not assert claim 66, the Federal Circuit has instructed that "both asserted and unasserted [claims] can . . . be valuable sources of enlightenment as to the meaning of a claim term." Phillips, 415 F.3d at 1314.

single dosage administration" means "formulated in a quantity that is taken or administered at one time." It points out that examples one and two disclose formulations with the same proportional concentrations of formoterol but different solution quantities. It then relies on extrinsic sources to establish that example two discloses "single use" formulations, and that this example establishes that formulation for "single dosage administration" turns on solution quantity, not a specific concentration of formoterol. Teva, on the other hand, argues simply that the specification provides an express definition for the disputed phrase because the only embodiment with a composition "formulated for single dosage administration" has a formoterol concentration of "about 100 µg/mL."

Dey points out that example one in the '344 patent describes two preparations of formoterol using a solution quantity of two liters of purified water: a "low dosage strength" formulation with a formoterol concentration of 85 µg/mL, and a "high dosage strength" formulation with a formoterol concentration of 170 µg/mL.[6] See '344, Example 1. It refers to these preparations as

[6] Example one describes the "low dosage strength" formulation as having 0.17 g of formoterol in two liters of water: 0.17 g formoterol / 2 L water = 0.085 g/L = 85 µg/mL. Example two also describes the "high dosage strength" formulation as having 0.34 g of formoterol in two liters of water: 0.34 g formoterol / 2 L water

"bulk" formulations.

Like its "bulk" formulation counterparts, example two of the '344 patent describes "unit dose" formulations with "low strength" and "high strength" formulations that have the same proportional formoterol concentrations as the formulations in example one: 85 µg/mL, and 170 µg/mL, respectively.[7] Id. at Example 2. Unlike the two liters of purified water needed for the "bulk" formulations, however, the "unit dose" formulations are prepared with the far smaller quantity of two milliliters of purified water.[8]

Because the specification does not define the term "unit dose," or provide additional insight into its meaning, Dey relies on an extrinsic source, the FDA Compliance Policy Guide, § 430.100 (1984) (dkt. no. 77-2), to establish that a "unit dose" is a "single dose." Further, relying on the Merriam-Webster's Medical Dictionary 218 (Merriam-Webster, Inc., 1996) (dkt. no. 69-19), it contends that a "dose" is "the measured quantity of a therapeutic

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= 0.17 g/L = 170 µg/mL.

[7] Example two describes the "low strength" unit dose as having 0.017 mg of formoterol in two milliliters of water: 0.17 mg formoterol / 2 mL water = 0.085 mg/mL = 85 µg/mL. Example two also describes the "high strength" unit dose as having 0.34 mg of formoterol in two milliliters of water: 0.34 mg formoterol / 2 mL water = 0.17 mg/mL = 170 µg/mL.

[8] 2,000 milliliters = 2 liters.

agent to be taken at one time." From these sources, Dey concludes that the "unit dose" formulations of example two are "single doses" that are "formulated for single dosage administration" because they are "formulated in a quantity that is taken or administered at one time."

Citing to Vitronics Corp. v. Conceptronic, Inc., Teva contends that Dey's reliance on extrinsic sources is improper because the specification provides an express definition that contradicts Dey's construction. 90 F.3d at 1582. In Vitronics, the Federal Circuit observed that the plaintiff's construction would prevent the specification's only embodiment from being covered by the claims. Id. at 1583. Given that "[s]uch an interpretation is rarely, if ever, correct," and can only be sustained with "highly persuasive evidence," the Federal Circuit rejected that construction, holding that the district court had relied improperly on extrinsic evidence providing a conflicting interpretation. Id.

In contrast to the construction in Vitronics, Dey's construction here is consistent with the specification's embodiments and claims, while Teva's construction would render claim 66, which is "formulated for single dosage administration," internally inconsistent and invalid since it obviously cannot have a formoterol concentrate of "59 µg/mL" and "100 µg/mL." See '344

patent, cls. 66, 53, 42. As discussed below, Teva fails to establish that the embodiment it cites defines the disputed phrase. Dey's construction, moreover, is consistent with the specification and would preserve the validity of claim 66.

Although extrinsic evidence is disfavored and often unreliable, a district court is not forbidden from relying on it in all cases. For example, in the landmark case of Phillips, the Federal Circuit, sitting en banc, recognized that extrinsic evidence may be helpful in determining a "reliable interpretation of patent claim scope" when it is "considered in the context of the intrinsic evidence." 415 F.3d at 1319. Thus, within the context of the intrinsic evidence, a district court may rely on extrinsic sources to educate itself "regarding the field of the invention," or to determine what a person of ordinary skill in the art would understand claim terms to mean. Id.

While an extrinsic source may never be used to contradict intrinsic evidence, the FDA Compliance Policy Guide relied on by Dey evinces a "commonly understood meaning" of the term "unit dose" that also comports with the intrinsic evidence. See id. at 1319, 1321. Therefore, when the definition of "unit dose" as a "single dose" is considered within the context of the specification and the claims as a whole, there being no intrinsic or extrinsic evidence

to the contrary, the Court concludes that Dey's reliance on an extrinsic source to define the "unit dose" formulations of example two as constituting "single dose" formulations is justified.

Defining "unit dose" as a "single dose," however, does not resolve whether "single dose" means "single dosage." "Dose" and "dosage" have distinct, yet similar, meanings. According to Merriam-Webster's Third International Dictionary, Unabridged 676 (Merriam-Webster, Inc., 3d ed. 2002), a "dose" is "the measured quantity of a medicine or other therapeutic agent to be taken at one time or in a period of time," while "dosage" is "the amount of medicine or other therapeutic agent . . . prescribed or proper for a given patient or illness." Despite subtle differences, a "single dosage" reasonably may be understood as an amount of medicine prescribed to be taken or administered at one time–- that is, a "dose." In this context, the Court finds no meaningful distinctions between the ordinary meaning of the terms "single dose" and "single dosage."

Given the lack of a meaningful distinction between the terms, and given that the defining feature of the "unit dose" formulations in example two is solution quantity, Dey's proposed construction, that formulation "for single dosage administration" turns on a solution quantity to be taken or administered at one time, and not

a specific concentration of formoterol, is persuasive.

While Teva correctly observes that the '344 patent does not expressly disclose whether a "unit dose" is "formulated for single dosage administration," it does not dispute that a person of ordinary skill in the art would have had access to the FDA Compliance Policy Guide issued in 1984, and that, as defined in that guide, the terms "unit dose" and "single dose" are generally synonymous. It also fails to identify any meaningful distinction between the terms "dose" and "single dosage." At bottom, therefore, Teva's contention that Dey's construction cannot be found in the text of the patent and that Dey's reliance on extrinsic evidence is improper, is unavailing.

Teva contends that the specification expressly defines "formulated for single dosage administration" as:

> In one embodiment, the formoterol fumarate is formulated for single dosage administration via nebulization at a concentration of about 100 µg/mL.

'344, col. 8, ll. 62-64. Because no other embodiments are described as being "formulated for single dosage administration," it insists that Dey acted as its own lexicographer and defined claims 62 and 65 of the '344 patent as having formoterol concentrations of about 100 µg/mL.

Fatal to this argument, however, is Teva's inability to

establish that Dey expressed a clear intent to define formulation "for single dosage administration" on the basis of a formoterol concentration of "about 100 µg/mL." Although the only embodiment in the specification disclosed as being "formulated for single dosage administration" has a formoterol concentration of "about 100 µg/mL," the specification includes no "'words or expressions of manifest exclusion or restriction'" establishing Dey's intent to limit and define the phrase as Teva construes it. I4I Limited Partnership, 598 F.3d at 843 (quoting Liebel-Flarsheim, 358 F.3d at 907-08). To the contrary, the specification is ambiguous on this issue; it neither states nor implies that all compositions "formulated for single dosage administration" must have a formoterol concentration of "about 100 µg/mL."

Well-settled principles of claim construction establish that "the scope of patent protection" will be defined by "[t]he claims, not specification embodiments." Kara Technology Inc. v. Stamps.com Inc., 582 F.3d 1341, 1348 (Fed. Cir. 2009). Thus, a court may not limit the scope of the claims to a "preferred embodiment or import a limitation from the specification into the claims." Id. (citing Phillips, 415 F.3d at 1323). Moreover, a claim generally will not be confined to the embodiments described in the specification "unless the patentee has demonstrated a 'clear intention' to limit

the claim's scope with 'words or expressions of manifest exclusion or restriction.'" I4I Limited Partnership v. Microsoft Corporation, 598 F.3d 831, 843 (Fed. Cir. 2010) (quoting Liebel-Flarsheim, 358 F.3d at 907-08).

Nothing in the '344 patent establishes that Dey used the embodiment to define the disputed phrase "with reasonable clarity, deliberateness, and precision." In re Paulson, 30 F.3d at 1480. Mindful of the Federal Circuit's repeated warnings against limiting the scope of the claims to specific embodiments, the Court rejects Teva's proposal to limit Dey's claims in this manner. See Kara Technology, 582 F.3d at 1347.

IV. CONCLUSION

For the reasons discussed, the Court **CONSTRUES** the contested claim terms and phrases as follows:

1. "Formulated at a concentration suitable for direct administration" means "ready to administer directly to a subject in need thereof, without mixing or diluting;"
2. "Pharmaceutical composition" means "a medicinal formulation containing an active drug and inert excipients;"
3. "Shelf life" means "the period of time during which a drug may be stored and remains suitable for use;" and

4. "Formulated for single dosage administration" means "formulated in a quantity that is taken or administered at one time."

Further, the Court adopts the parties' agreed claim constructions and **CONSTRUES** the following terms and phrases as follows:

1. "Stable during long term storage" means "the composition has an estimated shelf-life of greater than 1, 2 or 3 months usage time at 25° C and greater than or equal to 1, 2 or 3 years storage time at 5° C;"
2. "Article of manufacture" means something that "contains (1) packaging material, (2) a composition, which is useful for treatment, prevention or amelioration of one or more symptoms of diseases or disorders associated with undesired and/or uncontrolled bronchoconstriction, and (3) a label that indicates that the composition is used for treatment, prevention or amelioration of one or more symptoms of diseases or disorders associated with undesired and/or uncontrolled bronchoconstriction;"
3. "Packaging material or pharmaceutical packaging material" means "blister packs, bottles, tubes, inhalers, pumps, bags, vials, containers, syringes, bottles, and any

packaging material suitable for a selected formulation and intended mode of administration and treatment;"

4. "Label" means "Printed matter included with the article of manufacture that indicates that the composition is used for treatment, prevention or amelioration of one or more symptoms of diseases or disorders associated with undesired and/or uncontrolled bronchoconstriction."

5. "Nebulizer/Nebulized" means:

> "'Nebulizer': instrument that is capable of generating very fine liquid droplets for inhalation into the lung. Within this instrument, the nebulizing liquid or solution is atomized into a mist of droplets with a broad size distribution by methods known to those of skill in the art, including, but not limited to, compressed air, ultrasonic waves, or a vibrating orifice;"
>
> "'Nebulized': a liquid or solution composition that has been atomized into a mist of droplets with a broad size distribution by an instrument that utilizes methods known to those of skill in the art, including, but not limited to, compressed air, ultrasonic waves, or a vibrating orifice;" and

6. "Without dilution or other modification" means "a pharmaceutical composition that has not been diluted or changed in any other way."

It is so **ORDERED**.

The Court directs the Clerk to transmit copies of this Order to counsel of record.

DATED: June 17, 2011.

/s/ Irene M. Keeley
IRENE M. KEELEY
UNITED STATES DISTRICT JUDGE